

**Structured Product Labeling (SPL) OTC Sub-team Teleconference**  
February 14, 2011, 1:00 – 2:00 pm ET  
**Call Summary**

**I. Call Attendees (based on emails received)**

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

-  Paule Belony, The Belong Group LLC
-  Cheryl Blik, Teva Pharmaceuticals USA
-  Terry Brunone, GlaxoSmithKline
-  Gail Burke, Procter & Gamble
-  Amy Deuchler, Medline Industries, Inc.
-  Iris Feliciano, Tris Pharma
-  Lisa Fields, Blistex, Inc.
-  Chris Guay, Procter & Gamble
-  Michele Hewitt, Sandoz, Inc., Broomfield
-  Maureen Kapustynski, Cadbury
-  Ruth Kirkner, Teva
-  Diane O'Grady, Purdue Pharma, L. P.
-  Kathy Olgers, Perrigo Company
-  Alison Rago, Intagras
-  Janet Riffitts, McNeil Consumer Healthcare
-  Eva Rivera, Glemser Technologies Corporation
-  Howard Shatz, Data Conversion Laboratory, Inc.
-  Lonnie Smith, U.S. FDA
-  Carl Strotz, Pfizer Consumer Healthcare
-  Cynthia Thompson, Kimberly-Clark Corporation
-  Doris Vernicek, Johnson & Johnson Consumer & Personal Products  
Worldwide
-  Karen Vescovi, Church & Dwight Co., Inc.
-  Ann Marie Waller, Oraceutical, LLC
-  Carey Wilson, Intagras
-  Marcia Howard, CHPA staff (sub-team liaison)

- II. Next Standing Teleconference: March 14, 2011, 1:00pm ET (unless cancelled).**  
Standing calls for 2011 will be held on the second Monday of each month only and will be cancelled as appropriate.

### III. Discussion

#### A. Follow-up to December 10, 2010, SPL OTC sub-team call

- Based on the December discussion, the follow-up call with FDA staff as invited guests will now be handled in conjunction with the ER/DL sub-team.
- Representatives from other areas within FDA (in addition to Huascar Batista and Lonnie Smith) will also be invited to participate.
- Industry is asked to submit its questions and scenarios (general or hypothetical) to Paula Markert (SPL OTC sub-team leader), Terry Brunone (SPL WG co-leader), Pat Cowall-Hanover (ER/DL sub-team co-leader, or me (Marcia Howard, SPL OTC sub-team liaison) by Monday, [February 28<sup>th</sup>](#). This information will be combined with questions provided by the ER/DL team and submitted to FDA staff prior to the follow-up call. Please do not include any confidential or proprietary information; your identity will not be revealed to FDA unless you specifically request so.
- Due to the number of FDA staff calendars that will have to be coordinated to allow all to participate at one time, no date has been identified yet. The target timeframe is March/April 2011. The teleconference will likely be during the SPL OTC sub-team, ER/DL sub-team, or SPL Process Team standing call times. Details will be sent as soon as possible to update calendars.
- As during the December call, FDA will not be discussing or setting formal policy but will be providing information about its processes and obtaining feedback from industry.

#### B. Open Discussion

- OTC suffix information in SPL files posted to DailyMed
  - OTC suffixes in proprietary names are not currently displayed in the DailyMed listings. FDA's website for SPL product listings does include the suffixes.
- The new marketing category "drugs marketed for private label distributors only" will likely be used for very specific cases.
- Product listings & Importation delays
  - One company has had repeated delays for the same imported product in the same port because the contract manufacturer (CM) has not listed the product. These occurrences result in time delays and resource investment.
  - It appears that FDA continues to expect drug listings for the product by the CM which is the cause for the delays.
  - It was suggested that all documentation be retained as reference materials and that the firm contact the District Manager for a general discussion of the issue (not only when the product delay occurs).

- Delisting process for listing completed by the distributor
  - One company was advised not to delist products which were previously by the distributor if the product was still active under the distributor's NDC. (Inactive products were delisted as requested.)
  - This approach could lead to multiple distributors listed for one manufacturer.
  - This question should be submitted for the follow-up call.

#### IV. SPL Educational Forums/Information (*For Your Information*)

- A. **FDA Training Sessions:** Please visit the Data Standards Council website for details about upcoming agency training opportunities.

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>

- B. **SPL Process Communication Forum (Process Team):** Alternating Wednesdays 1:00 - 2:30 pm ET (unless cancelled; opposite to ERDL calls)  
Telephone number: 877-423-2663  
PIN#: 240184

Please email Process Team co-leaders Terry Brunone ([Theresa.M.Brunone@gsk.com](mailto:Theresa.M.Brunone@gsk.com)) or Mary Beth Wilusz ([mary\\_beth\\_wilusz@merck.com](mailto:mary_beth_wilusz@merck.com)) if you want to get the email information.

- C. **SPL ER/DL Sub-team calls:** Alternating Wednesdays at 1:00 pm ET (unless cancelled)

Please email sub-team co-leaders Patricia Cowall- Hanover ([COWALL-HANOVER.PATRICIA.L@LILLY.COM](mailto:COWALL-HANOVER.PATRICIA.L@LILLY.COM)) or Jessica Dunn Skorupski if you want to get the email information ([JSkorups@its.jnj.com](mailto:JSkorups@its.jnj.com)).

- D. **SPL Generics Sub-team calls:** Not currently holding regular calls.  
Please email sub-team leader Virginia Hogan if you want to get the email information ([Virginia.Hogan@tevausa.com](mailto:Virginia.Hogan@tevausa.com)).

- E. **Medical Products Sub-team calls:** Every other Thursday at 10:30 am EST  
Please email Sub-team leader Myron Finseth ([myron.finseth@medtronic.com](mailto:myron.finseth@medtronic.com)) if you want to join this sub-team.

Telephone Number: 770-657-9270  
Participant passcode: 745896

- F. **SPL Usage Discussion Group**  
Please email or call Terry Brunone ([Theresa.M.Brunone@gsk.com](mailto:Theresa.M.Brunone@gsk.com); +1-215-751-3210) or Gary Saner ([gsaner@reedtech.com](mailto:gsaner@reedtech.com); +1-610-731-7192) if you wish to join the discussion group.

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